Objections to March 29, 2017 Order Denying PAN/NRDC Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos

Submitted by:

Earthjustice

Objectors:

Pesticide Action Network

Natural Resources Defense Council

United Farm Workers

California Rural Legal Assistance Foundation

Farmworker Association of Florida

Farmworker Justice

GreenLatinos

Labor Council for Latin American Advancement

League of United Latin American Citizens

Learning Disabilities Association of America

National Hispanic Medical Association

Pineros y Campesinos Unidos del Noroeste

June 5, 2017

Docket No. EPA-HQ-OPP-2007-1005

TABLE OF CONTENTS

OBJECTIONS TO MARCH 29, 2017 ORDER DENYING PAN/NRDC PETITION TO REVOKE ALL TOLERANCES AND CANCEL ALL REGISTRATIONS FOR THE PESTICIDE CHLORPYRIFOS

INTRODUCTION AND SUMMARY

These objections seek: (1) reversal of the Environmental Protection Agency's ("EPA's") March 29, 2017 Order denying a 2007 petition to revoke all food tolerances for chlorpyrifos, a neurotoxic pesticide; and (2) an immediate final order revoking all chlorpyrifos tolerances. These objections are filed on behalf of Pesticide Action Network ("PAN"), Natural Resources Defense Council ("NRDC"), United Farm Workers, California Rural Legal Assistance Foundation, Farmworker Association of Florida, Farmworker Justice, GreenLatinos, Labor Council for Latin American Advancement, League of United Latin American Citizens, Learning Disabilities Association of America, National Hispanic Medical Association, and Pineros y Campesinos Unidos del Noroeste, by Earthjustice (collectively "Objectors").

PAN and NRDC filed the petition in 2007 asking EPA to revoke chlorpyrifos food tolerances and cancel all food uses of the pesticide. Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos (Sept. 12, 2017) ("2007 Petition") (EPA-HQ-OPP-2007-1005-0005). The 2007 Petition sought action by EPA on two critical issues left unaddressed when EPA re-registered chlorpyrifos in 2001 and 2006: (1) the growing scientific evidence that chlorpyrifos causes damage to children's brains from prenatal and early childhood exposures and that it does so at lower exposure levels than what EPA used in re-registering chlorpyrifos; and (2) harmful exposures to chlorpyrifos from pesticide drift and volatilization, which EPA never addressed in re-registering chlorpyrifos, despite numerous reported pesticide poisonings from chlorpyrifos every year and air monitoring detecting chlorpyrifos in school yards and residential neighborhoods in harmful amounts.

PAN and NRDC filed the 2007 Petition under the Federal Food, Drug and Cosmetic Act ("FFDCA"), which prescribes the required procedural and substantive outcomes. Procedurally, EPA may issue a proposed or final rule revoking the tolerances or an order denying the petition. 21 U.S.C. § 346a(d)(4)(A). Substantively, the FFDCA makes food safety the highest priority and constrains EPA's discretion accordingly. EPA may leave a tolerance in effect for a pesticide "only if the Administrator determines the tolerance is safe." *Id.* § 346a(b)(2)(A)(i). Conversely, the Administrator "shall modify or revoke a tolerance if the Administrator determines it is not safe." *Id.* The Act further constrains EPA by defining "safe" to mean that "the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure" to the pesticide. *Id.* § 346a(b)(2)(A)(ii).

As early as 2000, EPA noted that laboratory studies consistently showed that the developing brain can be harmed by low-level exposures to chlorpyrifos.[1] When EPA began to review the studies correlating chlorpyrifos exposures with damage to children's brains in response to the 2007 Petition, it found such a correlation. It submitted its analysis to EPA's

[1] EPA, Human Health Risk Assessment: Chlorpyrifos (June 8, 2000) at 131 ("Results of multiple studies have consistently shown that the developing brain is susceptible to chlorpyrifos treatment.").

Scientific Advisory Panel ("SAP") on multiple occasions beginning in 2008, and each time, the SAP confirmed EPA's conclusion that early life exposures to chlorpyrifos pose a risk of long-lasting, adverse cognitive, behavioral, and motor impairments. And both EPA and the SAP found that the exposures associated with serious damage to children's brains were far below the regulatory endpoint used by EPA in its 2001 and 2006 re-registration determinations and in establishing the chlorpyrifos tolerances currently in effect. *See infra* at 14-16.

These reviews culminated in EPA's official finding in its revised human health risk assessment, released in 2014, that chlorpyrifos causes long-lasting damage to children's brains at exposures lower than EPA's regulatory endpoint. *See infra* at 16-17. The 2014 risk assessment also documented unsafe chlorpyrifos exposures from drinking water contamination. In 2015, EPA proposed to revoke all chlorpyrifos tolerances based on these findings. 80 Fed. Reg. 69,080 (Nov. 6, 2015). In the proposed revocation rule, EPA explicitly and repeatedly found chlorpyrifos unsafe. *Id.* at 69,081-083, 69,097, 69,103, 69,105-106.

At the same time, the proposed revocation rule noted that EPA's 2014 risk assessment was under-protective in a fundamental way. EPA had not changed its regulatory endpoint, which continued to be based on poisoning risks, even though lower chlorpyrifos exposures caused brain impairments. EPA recognized that its 2014 risk assessment and 2015 proposed tolerance revocation did not address the greatest risks and most sensitive endpoint, as EPA policy requires.

EPA, therefore, continued to explore ways to establish an exposure limit that would protect children from neurodevelopmental harm. Each method it explored revealed more serious risks from chlorpyrifos than the 2014 risk assessment. In November 2016, EPA released its second revised human health risk assessment using a regulatory endpoint designed to guard against damage to children's brains. That risk assessment found unsafe exposures from every way that people come into contact with chlorpyrifos —on food, in drinking water, through pesticide drift, and from applying the pesticide or working in fields that had recently been sprayed.[2] EPA indicated it had found no chlorpyrifos uses that meet the FFDCA safety standard and all chlorpyrifos tolerances would need to be revoked. 81 Fed. Reg. 81,049, 81,050 (Nov. 17, 2016).

While the FFDCA does not establish a timeline for resolving petitions to revoke tolerances, EPA, like all federal agencies, must respond to administrative petitions "within a reasonable time." 5 U.S.C. § 555(b). EPA fell far short of this obligation with respect to the 2007 Petition to ban all food uses of chlorpyrifos. In 2015, the Ninth Circuit Court of Appeals found EPA guilty of "egregious" unreasonable delay and issued a writ of mandamus setting deadlines for EPA to take action. *In re PANNA v. EPA*, 798 F.3d 809, 811 (9th Cir. 2015). When EPA found that chlorpyrifos poses such serious risks that a nationwide ban was warranted, the court became persuaded that the time for study had passed and the time for action had arrived. *Id.* at 814. The court gave EPA a March 31, 2017 deadline to take final action on the 2007 Petition.

Something changed as that deadline approached, but it was neither the science, nor the legal mandates. A newly inaugurated President appointed a new EPA Administrator, Mr. Scott

[2] Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (Nov. 3, 2016) (EPA-HQ-OPP-2015-0653-0454).

Pruitt, and it fell to him to meet the court-ordered March 31, 2017 deadline. Administrator Pruitt chose not to finalize the revocation order, even though he could not make the safety findings required to keep chlorpyrifos in place. He decided to put off regulatory action. He issued an order on March 29, 2017, denominated "Chlorpyrifos: Order denying PANNA and NRDC's petition to revoke tolerances." 82 Fed. Reg. 16,581 (Apr. 5, 2017) ("Pruitt Order"). That Order, however, did not determine that the 2007 Petition should or could be denied on its merits. Nor did it make the safety findings required by law to take that course of action. Instead, the Pruitt Order postpones taking final action on the proposed tolerance revocation rule until some unspecified future time that could be five or more years off.

Such a postponement violates the FFDCA's substantive mandates. It leaves chlorpyrifos tolerances in place, but EPA has the authority to do so *only if* it finds chlorpyrifos safe. EPA has, however, repeatedly found chlorpyrifos to be unsafe. Under the FFDCA, EPA must revoke tolerances if it determines the tolerances unsafe. Revoking all chlorpyrifos tolerances is the only legally and scientifically defensible course of action. These objections ask EPA to rule on these objections within 60 days and revoke all chlorpyrifos on an expeditious basis.

PRELIMINARY MATTERS

I. NO FEE REQUIRED

Counsel for Objectors spoke with EPA's Office of General Counsel on June 1, 2017, and was informed that the fee described in 40 CFR 178.25(a)(5) is not required because EPA is prohibited from collecting such fees at this time. *See* 21 U.S.C. § 346a(m)(3) ("PROHIBITION. During the period beginning on October 1, 2007, and ending on September 30, 2017, the Administrator shall not collect any tolerance fees under paragraph (1)."). Therefore, no fee accompanies these objections.

II. THE ADMINISTRATIVE RECORD

Since completing re-registration of chlorpyrifos in 2006, EPA has engaged in extensive reviews and a rulemaking process regarding chlorpyrifos registrations and tolerances and has established three related dockets. The first docket, EPA-HQ-OPP-2007-1005, was opened in response to the 2007 Petition. The second docket, EPA-HQ-OPP-2008-0850, was opened when EPA began the registration review process for chlorpyrifos. The third docket, EPA-HQ-OPP-2015-0653, was opened when EPA initiated the tolerance revocation process after determining that chlorpyrifos was unsafe. EPA cites all three dockets as being relevant to its denial decision. 82 Fed. Reg. 16,581, 16,582 (Mar. 29, 2017). As such, all three dockets must be considered part of the administrative record for reviewing these objections to EPA's denial of the 2007 Petition.

In September 2016, many of the Objectors filed a Petition for Emergency and Ordinary Suspension of Chlorpyrifos Uses that Pose Unacceptable Risks to Workers and Petition to Cancel All Uses of Chlorpyrifos. After EPA released a revised human health risk assessment in November 2016 finding all food uses of chlorpyrifos unsafe, these groups withdrew the portion of the petition seeking an immediate suspension of chlorpyrifos uses that pose unacceptable risks to workers because revocation of chlorpyrifos food tolerances seemed inevitable and would end the uses and the associated harm to workers. The portion of the petition seeking cancellation of chlorpyrifos uses remains before EPA. EPA never opened a docket for the suspension and

cancellation petition, but the petition and supporting declaration and exhibits were submitted through comments to docket EPA-HQ-OPP-2015-0653 and are part of the record.[3]

Additionally, the administrative record must include all communications regarding chlorpyrifos between EPA (including the post-2016 election transition and beachhead teams) and Dow Agrosciences, CropLife America, the U.S. Department of Agriculture, and any other entity or agency that communicated with EPA outside of the public comment process.[4] *See, e.g., Bar MK Ranches v. Yuetter*, 994 F.2d 735, 739 (10th Cir. 1993) ("The complete administrative record consists of all documents and materials directly or indirectly considered by the agency").

III. NO EVIDENTIARY HEARING IS NEEDED IN LIGHT OF THE PURLEY SCIENTIFIC ISSUES RAISED IN THESE OBJECTIONS

The Objectors do not seek an evidentiary hearing because these objections present purely legal issues, namely whether EPA can leave chlorpyrifos tolerances in place when it has found chlorpyrifos unsafe. The FFDCA requires EPA to revoke chlorpyrifos tolerances in these circumstances and no evidentiary hearing is needed to do so.

BACKGROUND

I. THE LEGAL FRAMEWORK REQUIRES PROTECTION, PARTICULARLY OF CHILDREN, FROM HARMFUL PESTICIDES

A. The FFDCA Mandates Elimination of Harmful Pesticides From Our Food Supply

EPA regulates allowable contaminants, including pesticides, in our food supply under the FFDCA. For a pesticide to be permitted on food and imported or sold in interstate commerce, EPA must issue a tolerance that establishes the maximum residue of a pesticide allowed on food. 21 U.S.C. § 346a(b) & (c). EPA may "establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe." *Id.* § 346a(b)(2)(A)(i).

The Food Quality Protection Act ("FQPA"), passed unanimously in 1996, amended the FFDCA to require that EPA "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to pesticides. 21 U.S.C. § 346a(b)(2)(C)(ii)(I), (II).

---

[3] Earthjustice, *et al.*, Comments on EPA Proposal to Revoke Chlorpyrifos Tolerances (Jan. 17, 2017) (EPA-HQ-OPP-2015-0653-0661). The Petition for Emergency and Ordinary Suspension of Chlorpyrifos Uses that Pose Unacceptable Risks to Workers and Petition to Cancel All Uses of Chlorpyrifos and the Declaration of Philip J. Landrigan, M.D., M.Sc. in Support of Petition to Suspend and Cancel Chlorpyrifos Uses were submitted as attachments to these comments.

[4] Earthjustice, on behalf of PAN, submitted a Freedom of Information Act ("FOIA") request to EPA for these documents on March 15, 2017. EPA failed to substantively respond to that request within the statutory timeline, and to date has not released any documents related to PAN's FOIA request. On May 10, 2017, PAN filed a FOIA lawsuit against EPA seeking production of the requested records. *Pesticide Action Network of North America v. U.S. Environmental Protection Agency*, 3:17-cv-02706-SK (N.D. Cal. filed May 10, 2017).

The 1996 passage of the FQPA responded to a seminal 1993 National Academy of Sciences ("NAS") report criticizing EPA for regulating pesticides based on the effects on a 150-pound adult male.[5] It documented the ways that children are not "little adults" but have unique exposures from the foods they eat, their play, and their metabolism. For example, a 6-month old child drinks seven times more per body weight than an adult, inhales twice as much air, and puts its hands in its mouth more than is common later in life. The report also highlighted the windows of vulnerability — *in utero*, infancy, and adolescence — where children are particularly susceptible to the impacts of chemicals on their development. Chemical exposures can damage the developing brain at exposures less than those that affect adults.

The NAS recommended that EPA revamp and strengthen its regulation of pesticides to account for children's vulnerabilities, consumption patterns, and exposures. Because it would take time to fill gaps in knowledge, safeguards and methodologies, the NAS recommended that additional protection be afforded in the form of "uncertainty" or "safety factors." The NAS first described how EPA has regularly used uncertainty factors and then proposed an additional uncertainty factor for toxicity to infants and children and where data are incomplete on such toxicity or on children's exposures:

> In the absence of data to the contrary, there should be a presumption of greater toxicity to infants and children. To validate this presumption, the sensitivity of mature and immature individuals should be studied systematically to expand the current limited data base on relative sensitivity.

NAS Report at 9-10.

Heeding the NAS recommendations, the FQPA directs EPA to afford added protection to children based on their exposure patterns, their special sensitivities, such as during early or adolescent development, and gaps in available data to assess such risks. 21 U.S.C. § 346a(b)(2)(C)-(D). The statute explicitly requires EPA to assess the risk that a pesticide poses particularly to infants and children. 21 U.S.C. § 346a(b)(2)(C). Before EPA can establish a tolerance, the agency shall "ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure" to the pesticide, and shall "publish a specific determination regarding the safety of the pesticide chemical residue for infants and children." *Id.* §§ 346a(b)(2)(C)(ii)(I) & (II). In ensuring that the statutory safety standard is met, EPA must consider available information concerning "the special susceptibility of infants and children," including "neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals." *Id.* § 346a(b)(2)(C)(i)(II). EPA must also base its tolerance decision on available information about "food consumption patterns unique to infants and children." *Id.* §§ 346a(b)(2)(C)(i)(I) & (III).

One of the FQPA's key provisions is the requirement that EPA use an additional margin of safety to protect infants and children when establishing tolerances. The statute requires that: "an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre -and post-

[5] National Research Council, *Pesticides: Diets of Infants and Children* (1993) ("NAS Report"), https://www.nap.edu/catalog/2126/pesticides-in-the-diets-of-infants-and-children.

natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children." 21 U.S.C. § 346a(b)(2)(C). EPA can depart from this requirement and use a different margin of safety "only if, on the basis of reliable data, such margin will be safe for infants and children." *Id.*

In addition, because "[e]xposure to pesticide residues from ambient air sources is generally higher in areas close to agricultural lands," and "[b]ecause infants and children are subject to nondietary sources of exposure to pesticides," the NAS found that "it is important to consider total exposures to pesticides from all sources combined." NAS Report at 307, 309, 319. The FQPA requires EPA to "ensure that there is a reasonable certainty that no harm will result to infants and children *from aggregate exposure*" to a pesticide from all sources. 21 U.S.C. § 346a(b)(2)(C)(ii)(I), (II) (emphasis added). "Aggregate exposure" includes "all anticipated dietary exposures and all other exposures for which there is reliable information," including pesticide drift exposures. 21 U.S.C. § 346a(b)(2)(A)(ii); *see also id.* § 346a(b)(2)(D)(vi). The FQPA, therefore, requires an assessment based on aggregation of all exposures to a pesticide whether from eating foods, drinking water with residues of the pesticide, or contacting pesticide residues in and around the home or other places where people can be exposed. *Id.* § 346a(b)(2)(A)(ii), (C)(i)(I), (D)(vi). The FQPA also requires EPA to assess and protect against unsafe risks posed by cumulative exposures to all pesticides that share a "common mechanism of toxicity," as is the case with pesticides in the organophosphate family. *See id.* § 346a(b)(2)(C)(i)(III)-(D)(v).

B. Pesticide Use on Food Crops Is Regulated Under Overlapping Provisions of the Federal Insecticide, Rodenticide and Fungicide Act

EPA regulates use of pesticides in the United States under the Federal Insecticide, Rodenticide and Fungicide Act ("FIFRA"). Under FIFRA, EPA must establish a registration before a pesticide may generally be sold or used in the United States. 7 U.S.C. § 136a(a). To register or re-register a pesticide, EPA must determine that its use "will not generally cause unreasonable adverse effects on the environment," which includes risks to human health. *Id.* § 136a(c)(5)(D); *see id.* § 136(bb) (definition of "unreasonable adverse effects"). EPA has the authority to cancel a pesticide registration if the pesticide use "causes unreasonable adverse effects on the environment." *Id.* § 136d(b).

The two statutes' safety standards are intertwined through FIFRA's definition of "unreasonable adverse effects," which includes "a human dietary risk from residues that result from a use of a pesticide in or on any food inconsistent with the [FQPA] standard." 7 U.S.C. § 136(bb)(2). In other words, a pesticide may not be registered for a food use unless a food tolerance is in place, and whenever a food tolerance is revoked, the registration for use of the pesticide on that food crop must be cancelled. Because of this interdependence, the FQPA directs EPA to coordinate FQPA actions to revoke tolerances with any related, necessary FIFRA action. 21 U.S.C. § 346a(l).

Congress gave EPA a ten-year deadline, which ended in August 2006, to bring all food-use pesticides into compliance with these protective mandates. 21 U.S.C. § 346a(q)(1). The August 2006 deadline applied to both tolerances established under the FFDCA, as amended by the FQPA, and re-registration decisions under FIFRA.

To ensure that pesticides in use in the United States continue to meet the FQPA and FIFRA standards in light of the development of scientific methodologies and available scientific information on health effects and exposures, Congress required periodic review of pesticides every 15 years, but provided: "Nothing in this subsection shall prohibit the Administrator from undertaking any other review of a pesticide …." 7 U.S.C. § 136a(g) and § 136a(g)(1)(C). The first round of registration reviews of older pesticides, which includes chlorpyrifos, must be completed by October 1, 2022. *Id.* § 136a(g)(1)(A)(iii)(I).

II. EPA'S RE-REGISTRATION OF CHLORPYRIFOS

A. Chlorpyrifos

Chlorpyrifos is a widely used organophosphate pesticide first registered by EPA in 1965. It is used on an extensive variety of crops, including fruit and nut trees, vegetables, wheat, alfalfa, and corn. In 2006-2012, chlorpyrifos was applied to more than half of the country's apple and broccoli crops, 45% of onion, 46% of walnut, and 41% of cauliflower crops.[6] Five to eight million pounds are used annually in agriculture, including one million pounds on both corn and soybeans.[7]

Organophosphate chemicals were developed as nerve agents in World War II and adapted for use as insecticides after the war. They have deleterious effects on people who come into contact with them when they are used as insecticides.

Chlorpyrifos is acutely toxic and causes a significant number of acute pesticide poisoning incidents every year. Chlorpyrifos and other organophosphate pesticides do this by suppressing the activity of an enzyme called acetylcholinesterase, which regulates nerve impulses throughout the body. When cholinesterase activity is inhibited, nerves are over-stimulated, causing people to experience symptoms such as headaches, nausea, abdominal cramps, dizziness, difficulty breathing, vomiting, diarrhea, tremors, muscle spasms, seizures, skin rashes, and sometimes convulsions, respiratory paralysis, comas, and even death in extreme cases.

Widespread use of chlorpyrifos has exposed people through the air, in drinking water, and through the foods they eat. Monitoring by the California Department of Pesticide Regulation showed chlorpyrifos as having one of the highest number of detections in its 2011-2015 air monitoring, and water monitoring detected chlorpyrifos in 17.7% of samples, with 9.9%

[6] EPA, Chlorpyrifos Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures at 7 & Appendix C (July 13, 2012) (EPA-HQ-OPP-2008-0850-0105).
[7] *Id.*

exceeding the state's concentration limit.[8] In 2015, 61% of the air samples taken at a high school detected chlorpyrifos.[9]

In addition to poisonings, a growing body of published scientific research from both animal and epidemiology studies links exposure to chlorpyrifos with causing neurodevelopmental harm to children's brains. Children's brains are particularly vulnerable to damage from low-dose exposures because the placenta is not a barrier to passage of many toxic chemicals, including chlorpyrifos, from the mother to the fetus. An extensive body of published animal studies reveals cognitive, motor control, and social behavior impacts from chlorpyrifos exposures.

Additional evidence of neurodevelopmental harm from chlorpyrifos has come from three population cohorts that were studied by university research teams as part of the NIH-funded network of Centers for Children's Environmental Health. A research team at University of California-Berkeley followed a cohort of children born to farmworkers in Salinas Valley in California. A Mount Sinai School of Medicine study observed a New York City Hispanic population. A research team at Columbia University followed African American and Dominican children in New York City. The three studies each enrolled pregnant women and conducted long-term birth-cohort studies. Even though the studies were conducted in different parts of the country on different populations with different types of exposures, they produced strongly convergent results. All found that prenatal exposures to pesticides were statistically significantly correlated with cognitive impairments that persist into the school years, and the Columbia study was specific to chlorpyrifos. Prenatal exposures correlate with lasting functional harm to children's brains in the form of reduced IQ, loss of working memory, attention deficit disorders, and delayed motor development. Chlorpyrifos also has been found to cause physical changes in brain structure that may have long-lasting effects. Children living near agricultural fields suffer disproportionately from these effects. The Declaration of Philip J. Landrigan, M.D., M.Sc., who led the 1993 study that produced the NAS Report, describes the lines of evidence documenting damage to children's developing brains from chlorpyrifos and the other organophosphates (attached as Exhibit 1).

B. EPA's Re-registration Determinations for Chlorpyrifos

EPA used a two-part process for re-registering chlorpyrifos and the other organophosphate pesticides. First, it conducted risk assessments and made interim re-registration determinations for the individual organophosphates, which it did in 2001 for chlorpyrifos. Second, it conducted a cumulative risk assessment of all the organophosphates,

---

[8] Vidrio, E., Wofford, P., Segawa, R., Schreider, J. March 2013. Air Monitoring Network Results for 2011. Vol. 1. California Environmental Protection Agency, Department of Pesticide Regulation, http://www.cdpr.ca.gov/docs/emon/airinit/amn_vol1_final.pdf; and Zhang X., Starner K., Spurlock F. 2012. Analysis of Chlorpyrifos Agricultural Use in Regions of Frequent Surface Water Detections in California, USA . California Department of Pesticide Regulation, Environmental Monitoring Branch, Surface Water Protection Program. http://www.cdpr.ca.gov/docs/emon/pubs/ehapreps/analysis_memos/zhang_chlorpyrifos_report.pdf.

[9] http://www.cdpr.ca.gov/docs/emon/airinit/amn_2015_report_final.pdf (Shafter High School).

which it completed in 2006. The cumulative risk assessment did not result in changes in the interim re-registration and tolerance determinations for chlorpyrifos.

In its risk assessment for chlorpyrifos (as with the other organophosphates), EPA identified a level of 10% cholinesterase inhibition in red blood cells as the endpoint it would use in determining whether chlorpyrifos exposures violate the regulatory standards. In assessing risks from aggregate exposures to chlorpyrifos, EPA determined that home uses had to be cancelled. Children crawling on treated carpets and hugging pets after flea treatments faced unsafe exposures. Seeing the writing on the wall, the chemical makers agreed to cancel homeowner uses of chlorpyrifos in 2000.

EPA, however, never assessed the extent to which children in agricultural communities are exposed to chlorpyrifos through drift from agricultural sites to schools, day cares, playfields, and homes, or through residues their parents take home on their clothes. The failure to assess risks to and protect children in farmworker communities, who are primarily Latino and low-income, evinced a double standard that raises serious environmental justice concerns.

Nor did EPA protect the fetus and young children from neurodevelopmental harm, despite acknowledging in its 2000 human health risk assessment for chlorpyrifos that the fetus and young children are more sensitive to chlorpyrifos and that multiple studies consistently showed that the developing brain can be harmed by chlorpyrifos exposures.[10]

PAN, NRDC, and others commented on EPA's 2001 interim re-registration determination for chlorpyrifos, urging EPA to address pesticide drift and the mounting evidence of neuro-developmental impacts to children at low doses. The New York Attorney General also submitted comments emphasizing that the interim re-registration determination underestimated the risks of chlorpyrifos, particularly to children, and failed to make a finding that the pesticide is "safe" and complied with the FQPA.[11] The comments cited studies that suggested "that there is *no* level of exposure to chlorpyrifos that is without adverse effects on developmental neurotoxicity in the young...."[12] In 2006, after releasing its cumulative organophosphate risk assessment, EPA finalized its re-registration of chlorpyrifos without protecting children from drift or neurodevelopmental harm from chlorpyrifos and without addressing the public comments.

III. ADVOCACY TO CONVINCE EPA TO PROTECT CHILDREN FROM DRIFT AND NEURODEVELOPMENTAL HARM FROM CHLORPYRIFOS EXPOSURES

Farmworker and health advocates pursued three legal avenues to rectify EPA's failure to

---

[10] *See* NRDC Comments on Chlorpyrifos Interim Reregistration Decision (Jan. 14, 2002) (Docket ID No. OPP-34203G), attached Exhibit 2, (citing Human Health Risk Assessment - Chlorpyrifos (June 8, 2000), *available at https://archive.epa.gov/scipoly/sap/meetings/web/pdf/hed_ra.pdf*).

[11] Attorney General of the State of New York, comments on Chlorpyrifos Interim Reregistration Eligibility Decision and Interim Risk Management Decision pursuant to 66 Fed. Reg. 57,073-074 (Nov. 14, 2001) at 2, attached Exhibit 3.

[12] *Id.* at 19.

protect children from the hazards posed by chlorpyrifos. First, UFW, PAN, PCUN, and others, represented by Earthjustice and Farmworker Justice filed a federal district court challenge to the 2001 chlorpyrifos interim re-registration decision, in part, for failing to protect children and other bystanders from pesticide drift and failing to cancel uses that expose workers to admittedly excessive poisoning risks.[13] The parties negotiated principles on which the case could be settled with an EPA commitment to make a new regulatory decision for chlorpyrifos by 2010 that would address drift exposures to children and other bystanders. However, after the Ninth Circuit ruled in a case of first impression that challenges to FIFRA registration determinations must be brought in the courts of appeals within 60 days of the decision, the settlement fell apart.[14]

Second, PAN, UFW, PCUN, California Rural Legal Assistance Foundation, and others, represented by Earthjustice, and Farmworker Justice, petitioned EPA to address pesticide drift as mandated by the FQPA.[15] The Kids' Petition highlighted EPA's violation of its legal duty to protect children from all aggregate exposures to each pesticide in tolerance and re-registration determinations and asked EPA to expedite adoption of mitigation for airborne routes of exposure to organophosphates and n-methyl carbamates, another pesticide that suppresses cholinesterase, because of the heightened poisoning risks posed by these classes of pesticides. In March 2014, EPA responded to the petition, acknowledging its legal obligation to address pesticide drift under the FQPA and FIFRA. However, EPA indicated it would not protect children from drift until it reviewed pesticide registrations and tolerance decisions individually in registration review, and it refused to impose interim protections.[16] The petitioners filed administrative objections, which have not been resolved.[17]

Third, on September 12, 2007, PAN and NRDC submitted a petition asking EPA to ban chlorpyrifos based on the mounting evidence of risks from chlorpyrifos that were left unaddressed in EPA's 2001 and 2006 regulatory decisions. At its heart, the 2007 Petition raised two issues:

1. The 2007 Petition (at 17-21) challenged EPA's failure to account for risks to children and bystanders from chlorpyrifos drift and volatilization, as required by the FQPA. In support of this obligation, the petition presented the California Air Resources Board's air monitoring reports and data, which documented concentrations above EPA's levels of

---

[13] *UFW v. Administrator, EPA*, No. 07-3950-JF (N.D. Cal. filed Aug. 1, 2007).

[14] *UFW v. Administrator*, Stipulation of Voluntary Dismissal, Dkt. 98, No. 07-3950-JF (N.D. Cal. filed April 27, 2010); *see UFW v. Administrator, EPA*, 592 F.3d 1080 (9th Cir. 2010) (challenges to registration decisions must be brought in courts of appeals within 60 days, rather than in district court under a six-year statute of limitations as had previously been the case).

[15] *See* Pesticides In The Air – Kids At Risk: Petition to EPA to Protect Children From Pesticide Drift (October 13, 2009) (the "Kids' Petition") (EPA-HQ-OPP-2009-0825-0002).

[16] Agency Response to Pesticides In The Air – Kids At Risk: Petition to EPA to Protect Children From Pesticide Drift (March 31, 2014) at 2, 32-33 ("Agency Response to Kids' Petition") (EPA-HQ-OPP-2009-0825-0084).

[17] UFW, *et al.*, Written Objections to EPA's Response to Pesticides in the Air – Kids at Risk: Petition to EPA to Protect Children From Pesticide Drift (May 28, 2014). A court challenge to the decision not to impose interim protection was rejected. *PAN v. U.S.E.P.A.*, No. 14-71514 (9th Cir.).

concern near fields and in schoolyards, and community air monitoring, which showed widespread contamination in multiple locations and over a period of years, including in schoolyards.[18]

2. The 2007 Petition (at 6-9, 11-16) compiled the mounting evidence documenting serious cognitive and behavioral effects from low-dose chlorpyrifos exposures, including peer-reviewed scientific studies showing that children and infants exposed to chlorpyrifos exhibit long-lasting, and possibly permanent, impaired cognitive and behavioral development from early life exposure. The Petition cited concerns raised by members of EPA's Scientific Advisory Panel that EPA had failed to account for scientific evidence showing brain impacts from early life exposures to chlorpyrifos at lower doses than those used by EPA in its regulatory decisions. *Id.* at 13, 22-23.

IV. EPA'S ACTIONS IN RESPONSE TO THE 2007 PETITION

EPA has long recognized that organophosphates generally, and chlorpyrifos in particular, raise significant health issues. For this reason and because it would be reviewing the novel, complex scientific issues raised in the 2007 Petition and developing new scientific methodologies to do so, EPA decided to move up the registration review of chlorpyrifos in order to complete it several years in advance of the 2022 deadline.[19] EPA initiated the chlorpyrifos registration review and projected it would result in proposed regulatory decisions in 2014 and final ones in 2015. Chlorpyrifos Final Work Plan: Registration Review (Sept. 2009). PAN objected to the lengthy timetable, stating that uncertainties with respect to aspects of chlorpyrifos toxicity do not justify delaying action to protect children.[20]

As described above, the 2007 Petition sought a ban on use of chlorpyrifos on food based primarily on the need to protect children: (1) from exposure to chlorpyrifos from drift and volatilization; and (2) from exposures that could harm the developing brain. The petition raised other issues as well, which EPA separated from the two core issues. When faced with unreasonable delay litigation (*see infra*), EPA issued partial denials on various secondary issues, such as delays in completing endocrine disruption studies, cancer risks, that over-reliance on industry studies, and exporting chlorpyrifos to other countries.[21]

---

[18] Petition to Revoke All Tolerances and Cancel All Registrations for the Pesticide Chlorpyrifos at 17-21 (September 12, 2007), EPA-HQ-OPP-2007-1005.

[19] Declaration of Jack Housenger, Director of Health Effects Division of EPA's Office of Pesticide Programs ¶ 13, in *In re PANNA*, No. 12-71125 (9th Cir. July 23, 2012).

[20] Pesticide Action Network Comments (May 18, 2009) (EPA-HQ-OPP-2008-0850-0010).

[21] EPA's Partial Response to Chlorpyrifos Petition by NRDC & PANNA, letter from Dr. Steven Bradbury, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (July 16, 2012) (EPA-HQ-OPP-2007-1005-0095); Chlorpyrifos July 2014 Partial Petition Response, letter from Jack E. Housenger, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (July 15, 2014) (EPA-HQ-OPP-2007-1005-0098).

As to the heart of the petition, EPA engaged in several rounds of scientific review, solicited input from its Scientific Advisory Panel on numerous occasions, and developed methodologies to analyze, quantify, and for drift, to mitigate the risks.

A. Inhalation Exposures through Pesticide Drift and Volatilization

EPA's 2001 re-registration determination for chlorpyrifos ignored exposures through pesticide drift and volatilization on the theory that such exposures were exempted from the FQPA as occupational exposures. In responding to the Kids' Petition and in its preliminary human health risk assessment released in 2011, EPA acknowledged its legal obligation to assess and protect against drift and volatilization as aggregate exposures. Agency Response to Kids' Petition at 2, 32-34; 2011 PHHRA at 71-75. EPA committed to address such exposures in responding to the 2007 Petition and its registration review of chlorpyrifos and other pesticides.

1. EPA Has Appropriately Taken Steps to Reduce Exposures From Spray Drift, But These Steps Fail to Protect Children From Unsafe Exposures to Chlorpyrifos Through Drift

EPA has developed a standard methodology for assessing a pesticide's propensity to drift from the point of application offsite to schools, homes, day cares, playfields, and other places people gather and will be exposed. EPA models inhalation exposures from aerial applications, but for groundboom and airblast applications, it focuses only on dermal exposures when people come into contact with residues deposited on the ground. EPA justifies this omission because current pesticide labels prohibit applying pesticides in a manner that will allow drift to contact people. Public comments objected to this approach because of the extensive evidence that drift is reaching people and causing poisonings, thereby demonstrating that the label prohibition is not preventing harmful spray drift.[22]

EPA applied its standard methodology in assessing chlorpyrifos and found that chlorpyrifos can drift in harmful amounts. To protect children and other bystanders, EPA convinced the registrants to change chlorpyrifos labels by December 2012 to reduce application rates for aerial spraying, change nozzle types and droplet sizes, and impose no-spray buffers around sensitive sites frequented by non-occupational bystanders, especially children. Such sites include "residential lawns, pedestrian sidewalks, outdoor recreational areas such as school grounds, athletic fields, parks and all property associated with buildings occupied by humans for residential or commercial purposes. Sensitive sites include homes, farmworker housing, or other residential buildings, schools, day care centers, nursing homes, and hospitals."[23] The buffers are 10 feet for groundboom spraying, 10 feet for airblast applications, enlarged to 25-50 feet for large volume, medium or coarse droplet applications, and 10-100 feet for aerial spraying.

[22] Farmworker and Conservation Comments on Chlorpyrifos Revised Human Health Risk Assessment (Apr. 30, 2015) at 47 ("2015 Farmworker Comments") (EPA-HQ-OPP-2008-0850-0848) (citing Centers for Disease Control and Prevention investigation of pesticide drift causing poisonings of 20 workers between 30-350 feet from the application site).

[23] EPA, Chlorpyrifos – Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures (July 13, 2012) at 3.

In an interim response to the 2007 Petition, EPA stated that it was partially granting the Petition with respect to inhalation exposure risks and was reducing risks from primary spray drift by limiting application rates and imposing buffer zones around sensitive sites adjacent to agricultural applications.[24]

2. EPA Initially Found Harmful Exposures From Volatilization, But Reversed Course Based on Dow Studies That Have Been Heavily Criticized

EPA assessed risks from volatilization in its 2011 Preliminary Human Health Risk Assessment ("2011 PHHRA") based on ambient and application site monitoring. EPA's assessment showed that one-quarter of the acute ambient air concentrations resulted in risks of concern to residential bystanders, as did over half of the acute application site concentrations and most of the short- and intermediate-term application site concentrations.[25]

In 2013, drawing on methods used to assess bystander inhalation risks from fumigant pesticides and recommendations from a December 2009 Scientific Advisory Panel meeting, EPA conducted an assessment of volatilization risks from chlorpyrifos. EPA found that chlorpyrifos applied to fields can volatilize and harm people nearly a mile away (and likely farther): "Given the current available information and the state of the science concerning the volatilization of pesticides, this preliminary risk assessment indicates risks of concern are exceeded for bystanders."[26] EPA identified buffer zones that would be required to reduce off-site concentrations to safe levels. For example, for oranges, the average application rate is so high (greater than 2 pounds of active ingredient/acre) that the maximum buffers would need to be between 1,476 and 4,724 feet and whole field buffers would need to range from 623-2,838 feet, so large that continued use of chlorpyrifos would be infeasible.[27]

EPA subsequently reversed course based on two studies conducted by Dow AgroSciences, which purport to show that people will not experience adverse effects from volatilization exposures. Without submitting the studies to its Scientific Advisory Panel or obtaining other peer review, EPA accepted the studies and found that chlorpyrifos poses no risk of cholinesterase inhibition from volatilization. On July 15, 2014, EPA provided a partial response indicating that EPA will deny the volatilization component of the petition based on the

---

[24] Chlorpyrifos Petition – December 2012 Response, letter from Dr. Steven Bradbury, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (Dec. 18, 2012) (EPA-HQ-OPP-2007-1005-0096).

[25] Chlorpyrifos Preliminary Human Health Assessment for Registration Review (June 30, 2011) at 55 (EPA-HQ-OPP-2008-0850-0025).

[26] Chlorpyrifos: Preliminary Evaluation of the Potential Risks from Volatilization (Jan. 31, 2013) at 55 (assessment based on a study that measured the effects of aerosolized chlorpyrifos – the form chlorpyrifos takes when applied as a spray – and not the vapor form it takes after volatilization) (EPA-HQ-OPP-2008-0850-0114).

[27] *Id.* at 32-46.

Dow studies on chlorpyrifos vapors, as opposed to aerosols, which could have produced the monitoring concerns noted in 2011 and the risks of concern in the 2013 assessment.[28]

Public comments objected to EPA's use of the Dow studies without subjecting them to peer review. 2015 Farmworker Comments at 32-33. Comments explained that the Dow studies ignored the effects of temperature, soil moisture, and individual variation and submitted biomonitoring and incident reports showing poisoning incidents at distances as far away as one-half mile from the application site. *Id.* at 50-58. Comments also pointed out the lack of controls in the Dow study that demonstrated that the experiment was capable of successfully producing or detecting cholinesterase inhibition. Without such controls, the study results cannot be interpreted or used to claim that chlorpyrifos volatilization does not produce cholinesterase inhibition.[29]

B. EPA Found that Chlorpyrifos Exposures are Correlated with Harm to the Developing Brain at Exposures Far Below EPA's Regulatory Endpoint

As long ago as 2000, EPA noted that animal studies reveal that the developing fetus and young animals are more susceptible to chlorpyrifos than adults. Since that time, the scientific evidence of harm to children's brains from chlorpyrifos exposures has grown, with dozens of peer-reviewed scientific articles documenting statistically significant correlations between early life exposures and neurodevelopmental harm.

To respond to the 2007 Petition, EPA conducted a series of transparent and iterative reviews of the extensive scientific literature, including both animal and epidemiology studies, regarding neurodevelopmental harm from chlorpyrifos. It convened its Scientific Advisory Panel ("SAP") several times to review its assessments.

In 2008, EPA convened its SAP to review the significant new data since EPA's 2000 risk assessment. The SAP found that laboratory studies show that "gestational or early postnatal exposures can lead to neurochemical and behavioral alterations that persist into adulthood," including long-term neurobehavioral changes in motor and cognitive behaviors. 2008 SAP Report at 11-12.[30] The Panel found that "chlorpyrifos likely played a role in the birth and neurodevelopmental outcomes noted in the three cohort studies," and found the Columbia study the most sound and appropriate for use in assessing developmental toxicity of chlorpyrifos. *Id.* at 12, 37; *see also id.* at 43 ("chlorpyrifos is likely associated with adverse neurodevelopmental outcomes."). Finally, Panel members noted that the exposures in the Columbia study were below EPA's regulatory endpoint and of concern in light of evidence demonstrating that low levels of exposure to toxicants like lead, mercury, and PCBs are now known to produce significant adverse effects when they were previously thought to be harmful only at high levels.

---

[28] Chlorpyrifos July 2014 Partial Petition Response, letter from Jack E. Housenger, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (July 15, 2014).

[29] 2015 Farmworker Comments at 51; Earthjustice, *et al.*, Comments on EPA Proposal to Revoke Chlorpyrifos Tolerances (Jan. 17, 2017) at 21-22.

[30] FIFRA SAP Meeting Minutes No. 2008-04, A Set of Scientific Issues Being Considered by the EPA Regarding: The Agency's Evaluation of the Toxicity Profile of Chlorpyrifos (Sept. 2008), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2008-0274-0064.

Id. at 43.

In 2010, EPA convened its SAP to address how to incorporate epidemiology and incident data into risk assessments. EPA had developed a draft framework for incorporating epidemiology and human incident data into human health risk assessment. The Panel reviewed the draft and provided factors to be used to evaluate the quality of epidemiology studies, and identified ways such studies could be used in risk assessment.[31]

In July 2011, EPA released its Preliminary Human Health Risk Assessment, which confirmed, as the 2007 Petition claimed was legally required, the need to address drift, volatilization, and health impacts to children at low doses.[32] The assessment expressed concern that current tolerances may not afford sufficient protection to children from drinking water and drift exposures, particularly infants. Reader's Guide at 2-3; 2011 PHHRA at 17. As to the mounting evidence of neurodevelopmental impacts, EPA concluded that "chlorpyrifos likely played a role in long term neurological effects from early exposures that were evaluated in the epidemiology studies." Reader's Guide at 2-3. Despite these statements, EPA proposed to reduce the FQPA 10X safety factor to 1X, *i.e.*, to eliminate it. Numerous comments opposed eliminating the FQPA 10X safety factor, including comments submitted by the California Department of Pesticide Regulation observing that developmental neurotoxicity may be a more sensitive endpoint than cholinesterase inhibition and "[p]rotection against brain cholinesterase inhibition alone may be insufficient to protect against such effects."[33]

In 2012, EPA convened its SAP to review EPA's more comprehensive analysis of the neurotoxicity of chlorpyrifos. In its report, the SAP noted significant, long-term adverse effects on neurobehavioral development from chlorpyrifos in laboratory animal studies. It found that the epidemiology "studies show some consistent associations relating exposure measures to abnormal reflexes in the newborn, pervasive development disorder at 24 or 36 months, mental development at 7-9 years, and attention and behavior problems at 3 and 5 years of age." 2012 SAP at 17.[34] The Panel concurred with EPA and the 2008 SAP that "chlorpyrifos likely plays a role in impacting the neurodevelopmental outcomes examined in the three cohort studies," *id.* at 18, and it noted that "multiple lines of evidence suggest chlorpyrifos can affect neurodevelopment at levels lower than those associated with AChE inhibition." *Id.* at 19. Because the mode of action has not been identified, the SAP believed the cohort studies do not readily lend themselves as the basis for establishing the point of departure. However, the Panel expressed concern over EPA's focus on 10% cholinesterase inhibition because there is no

---

[31] FIFRA SAP Meeting Minutes No. 2010-03, A Set of Scientific Issues Being Considered by the EPA Regarding: Draft Framework and Case Studies on Atrazine, Human Incidents, and the Agricultural Health Study: Incorporation of Epidemiology and Human Incident Data into Human Health Risk Assessment (Feb. 2010), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2009-0851-0059.

[32] EPA, Reader's Guide to the Preliminary Human Health Risk Assessment for Chlorpyrifos at 1-3 (July 1, 2011) ("Reader's Guide") (EPA-HQ-OPP-2008-0850-0027).

[33] Comment submitted by California Department of Pesticide Regulation to EPA (Sept. 30, 2011) at 3 (EPA-HQ-OPP-2008-0850-0099).

[34] FIFRA SAP Meeting Minutes No. 2012-04, A Set of Scientific Issues Being Considered by the EPA Regarding: Chlorpyrifos Health Effects (Apr. 2012), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2012-0040-0029.

mechanism whereby a 10% AChE activity reduction in pregnant women would be responsible for a cognitive defect or developmental delay in their offspring." *Id.* at 25. The Panel advised EPA to explore ways to use the Columbia study to inform dose-response relationships. *Id.* at 19.

In December 2014, EPA released its Revised Human Health Risk Assessment for Chlorpyrifos ("2014 RHHRA")[35] and acknowledged the strong convergence in the findings from the animal studies and the three mother-child cohort studies. It found that the laboratory animal studies indicated "that gestational and/or postnatal exposure may cause persistent behavioral effects into adulthood." 2014 RHHRA at 25; *see id.* at 26 ("upon review of the published literature a pattern of neurodevelopmental adverse outcomes emerges."). It called the cohort studies "strong studies which support a conclusion that chlorpyrifos likely played a role in these outcomes." *Id.* at 33. More specifically, the studies:

> consistently identified associations with neurodevelopmental outcomes in relation to chlorpyrifos exposure. There is evidence of delays in mental development in infants (24-36 months), attention problems and pervasive developmental disorder in early childhood, and intelligence decrements in school age children who were exposed to chlorpyrifos or OP during gestation. Investigators reported strong measures of statistical association across several of these evaluations (odds ratios 2-4 fold increased in some instances) and observed evidence of exposure-response trends in some instances, e.g., intelligence measures.

Id at 42. EPA concluded "that these lines of evidence together support a conclusion that exposure to chlorpyrifos results in adverse neurodevelopmental outcomes in humans, at least under some conditions." *Id.* at 49. EPA also concluded that the range of exposures in the epidemiology studies were too low to result in cholinesterase inhibition. *Id.*; *see id.* at 47 ("it is unlikely that [cholinesterase] would have been inhibited by any meaningful or measureable amount, if at all" in the studies). EPA noted that the mode of action by which chlorpyrifos causes long-lasting damage to children's brains is uncertain, as is the particular exposure level at which such effects occur (apart from knowing it is lower than EPA's regulatory endpoint based on cholinesterase inhibition). Based on these uncertainties, EPA retained the FQPA 10X safety factor for infants, children, youth, and women of child-bearing years. *Id.* at 49.

EPA continued to use cholinesterase inhibition as its regulatory endpoint in its 2014 risk assessment, despite acknowledging that the harm to children's brains occurred at lower exposures and is therefore the most sensitive endpoint. EPA then used a model developed by Dow Agrosciences (called a physiologically based pharmacokinetic or PBPK model) to estimate doses in people associated with cholinesterase inhibition. Because the model uses human data, at least in part, EPA decided it could eliminate the traditional 10X safety factor that accounts for uncertainty in extrapolating from animal tests to human impacts (inter-species safety factor). It also reduced by half or more the other traditional 10X safety factor designed to account for variability and sensitivity within human populations (intra-species factor), believing that the human data and the model incorporate such human variability.

---

[35] Chlorpyrifos: Revised Human Health Risk Assessment for Registration Review (Dec. 29, 2014) (EPA-HQ-OPP-2008-0850-0195).

Public comments objected to the reduction of these traditional safety factors because the Dow model estimates exposures associated with the cholinesterase inhibition endpoint, and neurodevelopmental harm occurred from prenatal exposures far below those that would result in 10% cholinesterase inhibition.[36] In addition, EPA's Scientific Advisory Panel had found serious problems with the Dow model in 2011, yet EPA never submitted the model, as subsequently modified, for further review by the Panel, nor did EPA explain how the modifications corrected the problems identified by the 2011 SAP. 2011 SAP at 11, 13-17.[37] The model uses data from two studies that deliberately dosed people, and EPA cannot rely on such deliberate human testing without ensuring the tests meet rigorous ethical and scientific standards. 40 C.F.R. §§ 26.1701-.1706. Comments objected to EPA's use of the Dow model because EPA did not obtain review of the studies under current legal standards by its Human Studies Review Board and because of ethical flaws in using Dow employees in one study and in its misleading informed consent, as well as scientific deficiencies. 2015 Farmworker Comments at 36-42.

Even though the 2014 RHHRA used an endpoint that fails to protect children from neurodevelopmental harm and shrunk the traditional safety factors, it found that a substantial number of chlorpyrifos uses will result in exposures that exceed EPA's drinking water levels of concern. 80 Fed. Reg. at 69,083. EPA determined that the drinking water exceedances were likely to be conservative because its modeling is validated by empirical water monitoring data and its modeling is based on a single application.[38]

V. THE UNREASONABLE DELAY LITIGATION

It took a series of unreasonable delay lawsuits to obtain EPA action on the 2007 Petition. Shortly after PAN filed the 2007 Petition, EPA found that the petition met the legal requirements for FFDCA petitions and published a notice in the Federal Register requesting public comments. 72 Fed. Reg. 58,845 (Oct. 17, 2007). After three years passed without a response to the 2007 Petition, PAN and NRDC filed an unreasonable delay lawsuit, which they settled based on EPA's commitment to respond to the Petition by the end of November 2011. *NRDC v. EPA*, No. 10-05590-CM, Dkt. No. 17, at 2-3 (S.D.N.Y. Dec. 21, 2010) (Stipulation).

After EPA missed the 2011 deadline, PAN and NRDC brought a second delay lawsuit. EPA issued a partial response to the 2007 Petition, promising a complete final response in

---

[36] 2015 Farmworker Comments at 28-32. *See also*, Comment submitted by Elaine M. Faustman, Ph.D. DABT, on behalf of the Institute of Risk Analysis and Risk Communication and the Center for Child Environmental Health Risks Resarch at the University of Washington (EPA-HQ-OPP-2008-0850-0829); Comment submitted by Robin M. Whyatt, Professor, Columbia University, Dale Hattis, Research Professor, Clark University and Theodore Slotkin, Duke University School of Medicine (EPA-HQ-OPP-2008-0850-0510).

[37] FIFRA SAP Meeting Minutes No. 2011-03, A Set of Scientific Issues Being Considered by the EPA Regarding Chlorpyrifos Physiologically Based Pharmacokinetic and Pharmacodynamis (PBPK/PD) Modeling Linked to Cumulative and Aggregate Rise Evaluation System (CARES) (Feb. 2011), *available at* https://www.regulations.gov/document?D=EPA-HQ-OPP-2010-0588-0038.

[38] Chlorpyrifos: Updated Drinking Water Assessment for Registration Review (Dec. 23, 2014) (EPA-HQ-OPP-2008-0850-0198).

December 2012.[39] While EPA's first interim response addressed six points made in the 2007 Petition, it did not determine whether EPA would ban chlorpyrifos. *See id.* The only practical effect of EPA's July 2012 partial decision consisted of EPA's announcement that the chlorpyrifos registrants had agreed to a spray drift mitigation package that calls for small no-spray buffers (most were only ten feet) around school grounds, homes, residential lawns, athletic fields, nursing homes, hospitals, sidewalks, and other places frequented by bystanders.[40] EPA then missed the December 2012 deadline for issuing a response to the 2007 Petition, but it promised a final response by February 2014.[41]

In 2013, the Ninth Circuit Court of Appeals decided not to order EPA to respond to the 2007 Petition because the agency had "set forth a concrete timeline for final agency action that would resolve the 2007 Petition by February 2014." *In re PANNA*, 532 F. App'x 649, 651 (9th Cir. 2013).

EPA missed its February 2014 deadline. In July 2014, EPA issued another partial response and reversed its earlier preliminary determination that chlorpyrifos volatilization presents risks that warrant large, no-spray buffers (in some instances many thousands of feet) around schools, homes, and other places frequented by people. EPA based this reversal on two new studies conducted by Dow AgroSciences LLC, the primary chlorpyrifos registrant.[42] In that partial response, EPA indicated that it planned to release a revised human health risk assessment for public comment in December 2014, along with either a proposed rule revoking tolerances for chlorpyrifos or a proposed order denying the 2007 Petition, and that it would issue any final denial of the 2007 Petition by the summer of 2015.

After EPA missed its February 2014 deadline, PAN and NRDC filed a third unreasonable delay case seeking a writ of mandamus from the Ninth Circuit directing EPA to act. When the case was argued on June 4, 2015, EPA told the court that it would complete its preliminary review of the public comments on the 2014 risk assessment by June 30, 2015 and determine whether it would deny or grant the 2007 Petition, in whole or in part. On June 10, 2015, the court ordered EPA to file a status report by June 30, 2015 informing the court which path it would take and proposing a timeline for final resolution of the 2007 Petition. *In re PANNA*, 790 F.3d 875 (9th Cir. 2015). EPA's June 30, 2015 status report revealed that EPA had become convinced that revocation of all chlorpyrifos food tolerances was warranted because of drinking

---

[39] EPA's Partial Response to Chlorpyrifos Petition by NRDC & PANNA, letter from Dr. Steven Bradbury, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (July 16, 2012).

[40] *Id.* (citing Chlorpyrifos – Evaluation of the Potential Risks from Spray Drift and the Impact of Potential Risk Reduction Measures (July 13, 2012) at 3).

[41] *See* Chlorpyrifos Petition – December 2012 Response, letter from Dr. Steven Bradbury, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (Dec. 18, 2012) (EPA-HQ-OPP-2007-1005-0096); Chlorpyrifos Petition – January 2013 Response, letter from Dr. Steven Bradbury, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (Jan. 25, 2013) (EPA-HQ-OPP-2007-1005-0097); EPA Response to Petition for Writ of Mandamus, in *In re PANNA*, No. 12-71125 (9th Cir. July 24, 2012).

[42] Chlorpyrifos July 2014 Partial Petition Response, letter from Jack E. Housenger, Director, EPA Office of Pesticide Programs, to Aaron Colangelo and Margaret Reeves, Ph.D (July 15, 2014) at 2-5.

water contamination. Because it offered no definitive timetable for initiating and completing such a revocation rule, PAN and NRDC asked the Court to do so.

In August 2015, the Ninth Circuit issued a writ of mandamus setting deadlines for EPA action. The decision began as follows:

> Although filibustering may be a venerable tradition in the United States Senate, it is frowned upon in administrative agencies tasked with protecting human health. Pesticide Action Network North America and the Natural Resources Defense Council have been waiting for years for the United States Environmental Protection Agency to respond to their administrative petition requesting a ban on the pesticide chlorpyrifos. Instead, they've received a litany of partial status reports, missed deadlines, and vague promises of future action. We recognize the scientific complexity inherent in evaluating the safety of pesticides and the competing interests that the agency must juggle. However, EPA's ambiguous plan to possibly issue a proposed rule nearly nine years after receiving the administrative petition is too little, too late. This delay is egregious and warrants mandamus relief. We order EPA to issue a full and final response to the petition no later than October 31, 2015.

In re PANNA, 798 F.3d 809, 811 (9th Cir. 2015); *see id.* at 813 ("Issuing a writ of mandamus is necessary to end this cycle of incomplete responses, missed deadlines, and unreasonable delay.").

The court explained that the circumstances had changed in two significant respects since the court rejected the earlier request in 2013. First, in 2006, after residential uses had ended, EPA had found the remaining chlorpyrifos uses to be safe and it had not overturned those findings in its 2011 preliminary human health risk assessment. That changed in 2014 when EPA found agricultural uses of chlorpyrifos unsafe due to drinking water contamination and also noted serious risks to farmworkers who apply chlorpyrifos or who enter fields after chlorpyrifos has been sprayed. The court found that "EPA offers no acceptable justification for the considerable human health interests prejudiced by the delay. In view of EPA's own assessment of the dangers to human health posed by this pesticide, we have little difficulty concluding it should be compelled to act quickly to resolve the administrative petition." *Id.* at 814.

Second, EPA told the court that complex regulatory proceedings may be needed to effectuate a chlorpyrifos ban. While it indicated it would try to negotiate a settlement with the registrants, if voluntary action did not eliminate unsafe exposures, EPA would need to take regulatory action to revoke chlorpyrifos food tolerances. Yet EPA offered the court no concrete timeline for proposing, let alone finalizing, a tolerance revocation rule. Calling this approach "a roadmap for further delay," the court concluded that EPA had "stretched the 'rule of reason' beyond its limits." *Id.*

The court ordered EPA either to initiate a tolerance revocation rulemaking or deny the 2007 Petition by October 31, 2015, and if it proposed to revoke tolerances, to provide a timeline for finalizing that proposed rule. *Id.* at 815. After EPA proposed to revoke all chlorpyrifos tolerances, the court directed EPA to take final action on that proposal by December 30, 2016. *In re PANNA*, No. 14-72794, Order (9th Cir. Dec. 10, 2015). The court also directed EPA to file

a status report on June 30, 2016, detailing the steps taken to meet the final deadline and indicating that the court would extend the deadline only if EPA showed that extraordinary circumstances made compliance impracticable. *Id.*

EPA sought an additional six months to conduct further scientific review, referring to its efforts to quantify the exposures associated with damage to children's brains for use in a quantitative risk assessment and to continue its assessment of drinking water risks. The court denied the request, calling it "another variation on a theme 'of partial reports, missed deadlines, and vague promises of future action' that has been repeated for the past nine years." *In re PANNA*, No. 14-72794, Order (9th Cir. Aug. 12, 2016). The court found no justification for further delay in responding "to the pressing health concerns presented by chlorpyrifos." *Id.*; *see id.* ("a claim of premature rulemaking has come and gone."). The court nonetheless gave EPA until March 31, 2017 to take final action and stated: "This is the final extension, and the court will not grant any further extensions." *Id.*

VI. EPA PROPOSED TO REVOKE ALL TOLERANCES BECAUSE IT FOUND CHLORPYRIFOS UNSAFE

In October 2015, EPA proposed to revoke all chlorpyrifos tolerances because of drinking water contamination. 80 Fed. Reg. 69,080 (Nov. 6, 2015). EPA concluded that it "is unable to conclude that the risk from aggregate exposure from the use of chlorpyrifos meets the safety standard of the Federal Food, Drug, and Cosmetic Act (FFDCA)." *Id.*; *see also id.* at 69,081 ("EPA cannot, at this time, determine that aggregate exposure to residues of chlorpyrifos, including all anticipated dietary exposures and all non-occupational exposures for which there is reliable information, are safe."). "Because EPA is unable to determine at this time that aggregate exposures to chlorpyrifos are safe, EPA is proposing to revoke these tolerances in response to a Petition from PANNA and the Natural Resources Defense Council (NRDC) to revoke all chlorpyrifos tolerances...." *Id.* at 69,081.

Drinking water contamination proved to be the impetus for the proposed revocation. EPA relied on its 2014 risk assessment, which it called "a highly sophisticated assessment of hazard and exposure to chlorpyrifos and its oxon." *Id.* at 69,082. Based on that assessment, EPA determined that multiple chlorpyrifos uses exceed EPA's drinking water level of concern with considerable frequency and present a risk of concern with infants most at risk. *Id.* at 69,082-83. EPA found all chlorpyrifos uses under current labels to be unsafe. *Id.* at 69,083. The proposed rule held open the possibility that registrants and growers might be able to submit additional information and propose label modifications to prevent some watersheds from being at risk from certain chlorpyrifos uses. *Id.* at 69,080.

The proposed rule also acknowledged that the 2014 risk assessment was under-protective of children because it was based on cholinesterase inhibition and the harm to children's brains is associated with lower exposures. EPA indicated that it would continue to review the evidence of long-lasting neurodevelopmental harm to children from low-level exposures and to try to incorporate that evidence into its risk assessment and regulatory determination.

In public comments to EPA, farmworker and health advocates submitted recently published scientific articles that continued to strengthen the correlation between low-level